K062128

510(k) Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Lorraine H Piestrak
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P.O. Box 6101
Newark, DE 19714-6101

AUG 2 1 2006

Date of Preparation: July 25, 2006

Name of Products:

Dimension Vista™ Creatine Kinase MB Isoenzyme (CKMB) Flex® reagent cartridge
Dimension Vista™ Hemoglobin A1c Kit (HA1C)
Dimension Vista™ Urine Amphetamine/Methamphetamine Screen (AMPH) Flex® reagent cartridge
Dimension Vista™ Urine Barbiturates Screen (BARB) Flex® reagent cartridge
Dimension Vista™ Urine Benzodiazepines Screen (BENZ) Flex® reagent cartridge
Dimension Vista™ Urine Cocaine metabolite Screen (COC) Flex® reagent cartridge
Dimension Vista™ Urine Ecstasy Screen (EXTC) Flex® reagent cartridge
Dimension Vista™ Urine Methadone Screen (METH) Flex® reagent cartridge
Dimension Vista™ Urine Opiates Screen (OPI) Flex® reagent cartridge
Dimension Vista™ Urine Phencyclidine Screen (PCP) Flex® reagent cartridge
Dimension Vista™ Urine Cannabinoids Screen (THC) Flex® reagent cartridge

FDA Classification Name:

Classification Name:	Common/Usual Name:
862.1215 Differential Rate Kinetic Method, Cpk or Isoenzymes	Creatine kinase isoenzyme test system
864.7470 Assay, Glycosylated Hemoglobin	Glycosylated hemoglobin test system
862.3100 Enzyme Immunoassay, Amphetamine	Amphetamine test system
862.3150 Enzyme Immunoassay, Barbiturate	Barbiturate test system
862.3170 Enzyme Immunoassay, Benzodiazepine	Benzodiazepine test system
862.3250 Enzyme Immunoassay, Cocaine and Metabolites	Cocaine and metabolite test system
862.3100 Enzyme Immunoassay, Amphetamine	Ecstasy test system
862.3620 Enzyme Immunoassay, Methadone	Methadone test system
862.3650 Enzyme Immunoassay, Opiates	Opiate test system
862.3100 Enzyme Immunoassay, Phencyclidine	Phencyclidine test system
862.3870 Enzyme Immunoassay, Cannabinoids	Cannabinoid test system

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

New Product	Predicate	Predicate 510(k) #	Device class	Regulation	Product Code
Dimension Vista™ CKMB Flex® reagent cartridge	Dimension® Flex® CKMB reagent cartridge	K943024	II	862.1215	JHS
Dimension Vista™ HA1C Kit	Dimension® HA1C Kit	K011852	II	864.7470	LCP
Dimension Vista™ AMPH Flex® reagent cartridge	Dimension® Flex® AMPH reagent cartridge	K040133	II	862.3100	DKZ
Dimension Vista™ BARB Flex® reagent cartridge	Dimension® Flex® BARB reagent cartridge	K000459	II	862.3150	DIS
Dimension Vista™ BENZ Flex® reagent cartridge	Dimension® Flex® BENZ reagent cartridge	K000458	II	862.3170	JXM
Dimension Vista™ COC Flex® reagent cartridge	Dimension® Flex® COC reagent cartridge	K033713	II	862.3250	DIO
Dimension Vista™ EXTC Flex® reagent cartridge	Dimension® Flex® EXTC reagent cartridge	K053337	II	862.3100	DKZ
Dimension Vista™ METH Flex® reagent cartridge	Dimension® Flex® METH reagent cartridge	K000466	II	862.3620	DJR
Dimension Vista™ OPI Flex® reagent cartridge	Dimension® Flex® OPI reagent cartridge	K003209	II	862.3650	DJG
Dimension Vista™ PCP Flex® reagent cartridge	Dimension® Flex® PCP reagent cartridge	K000462	II	862.3100	LCM
Dimension Vista™ THC Flex® reagent cartridge	Dimension® Flex® THC reagent cartridge	K000461	II	862.3870	LDJ

Device Description:

Dade Behring Dimension Vista™ Flex® reagent cartridges and the HA1C kit are prepackaged in-vitro diagnostic test methods (assays) that are specifically designed to be used on the Dade Behring Dimension Vista™ Integrated system, a floor model, fully automated, microprocessor-controlled, integrated instrument system. The Dimension Vista™ system was previously cleared

with seven associated test methods (K051087). This Special 510(k) is submitted for a packaging modification to *in-vitro* diagnostic devices that have been cleared under the 510(k) process for use on Dimension® clinical chemistry systems. The packaging change is to allow use on the Dimension Vista™ system.

The reagents contained in the Dimension Vista™ Flex® reagent cartridges are the same as those contained in the Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Dade Behring analyzers. The calibrator included in the Dimension Vista™ HA1C kit is the same product (unchanged) as that used in the Dimension® HA1C Kit. The packaging modification, does not affect the intended use of the devices, nor does it alter the fundamental scientific technology of the devices.

Intended Use:

Creatine Kinase MB Isoenzyme
The CKMB method is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB Isoenzyme in human serum and plasma on the Dimension Vista™ System.

Hemoglobin A1c Kit
The HA1C assay used on the Dimension Vista™ System is an *in vitro* diagnostic assay for the quantitative determination of percent hemoglobin A1c (HbA1c) in anticoagulated whole blood. Measurements of percent hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

Urine Amphetamine/Methamphetamine Screen
The AMPH method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of amphetamines in human urine using a cutoff of either 300, 500, or 1000 ng/mL on the Dimension Vista™ System. Measurements obtained with the AMPH method are used in the diagnosis and treatment of amphetamines use or overdose.

Urine Barbiturates Screen
The BARB method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of barbiturates in human urine on the Dimension Vista™ System. Measurements obtained with the BARB method are used in the diagnosis and treatment of barbiturates use or overdose.

Urine Benzodiazepines Screen
The BENZ method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of benzodiazepines in human urine on the Dimension Vista™ System. Measurements obtained with the BENZ method are used in the diagnosis and treatment of benzodiazepines use or overdose.

Urine Cocaine metabolite Screen
The COC method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine using a cutoff of 150 or 300 ng/mL on the Dimension Vista™ System. Measurements obtained with the COC method are used in the diagnosis and treatment of cocaine use or overdose.

Urine Ecstasy Screen
The EXTC method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of methylenediosymethamphetamine (MDMA) and closely related drugs in human urine using a cutoff of 300 or 500 ng/mL on the Dimension Vista™ System. Measurements obtained with the EXTC method are used in the diagnosis and treatment of ecstasy use or overdose.

Urine Methadone Screen
The METH method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of methadone in human urine on the Dimension Vista™ System. Measurements obtained with the METH method are used to detect methadone use or overdose, and to determine compliance with methadone maintenance treatment.

Urine Opiates Screen
The OPI method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of opiates in human urine on the Dimension Vista™ System. Measurements obtained with the OPI method are used in the diagnosis and treatment of opiates use or overdose.

Urine Phencyclidine Screen
The PCP method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of phencyclidine in human urine on the Dimension Vista™ System. Measurements obtained with the PCP method are used in the diagnosis and treatment of phencyclidine use or overdose.

Urine Cannabinoids Screen
The THC method is an *in vitro* diagnostic test for the qualitative and semi-quantitative determination of cannabinoids in human urine on the Dimension Vista™ System. Measurements obtained with the THC method are used in the diagnosis and treatment of cannabinoids use or overdose.

Comparison to Predicate Device:
Both the Dimension Vista™ Flex® reagent cartridges/kit and the predicate Dimension® Flex® reagent cartridges/kit contain prepackaged reagents in flexible plastic cartridges. A comparison of the important similarities and differences between the two Flex® cartridges is provided in the following table:

Feature	Dimension Vista™ Flex® reagent cartridge	Dimension® Analyzer Flex® reagent cartridge
Reagents	Prepackaged, 12-well plastic, Dade Behring Flex® reagent cartridges	Prepackaged, 6 & 8 well plastic, Dade Behring Flex® reagent cartridges
Intended Use	*in vitro* diagnostic use	*in vitro* diagnostic use
Indications for Use	Same as Dimension® analyzer	As described in 510(k)s for each previously cleared method.
Final concentration of sample/reagent ratio in test milieu	Same as Dimension® analyzer	As described in 510(k)s for each previously cleared method
Tablet Sizes	7/32"	7/32" & 9/32"
Total tests contained in each Flex® cartridge	Approximately three times more than contained in Dimension® Flex® reagent cartridges	As described in 510(k)s for each previously cleared method.
Calibration	30 to 90 days (determined for each method)	30 to 90 days As described in 510(k)s for each previously cleared method.
HA1C calibrator	Same product as Dimension® HA1C calibrator	As described in K011852

Comments on Substantial Equivalence:

The Dade Behring Dimension Vista™ Flex® reagent cartridges and the Dimension® Flex® reagent cartridges are designed similarly for the same purpose. Both contain prepackaged reagents for *in-vitro* diagnostic tests that are processed on microprocessor-controlled, integrated instrument systems to analyze a variety of analytes in human specimens.

The reagents contained in the Dimension Vista™ Flex® reagent cartridges are the same as those contained in the Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Dade Behring analyzers. The calibrator included in the Dimension Vista™ HA1C kit is the same product (unchanged) as that used in the Dimension® HA1C Kit. The packaging modifications do not affect the intended use of the devices, nor do they alter the fundamental scientific technology of the devices.

Comparative testing described in the protocol included in this submission demonstrates substantially equivalent performance.

Conclusion:
The Flex® reagent cartridges/kit, containing reagents for testing CKMB, HA1C, AMPH, BARB, BENZ, COC, EXTC, METH, OPI, PCP, THC on the Dimension® Vista™ Integrated system are substantially equivalent in design, principle, and performance to the Dimension® system Flex® reagent cartridges/kit. They have the same intended use and indications for use. Comparative testing also demonstrates substantially equivalent performance.

Lorraine H Piestrak
Regulatory Affairs & Compliance Manager
July 25, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lorraine Piestrak
Regulatory Affairs & Compliance Manager
Dade Behring, Inc.
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Newark, DE 19714-6101

AUG 2 1 2006

Re: k062128
Trade/Device Name: Dimension Vista™ Creatine Kinase MB Isoenzyme (CKMB) Flex® reagent cartridge
Dimension Vista™ Hemoglobin A1c Kit (HA1C)
Dimension Vista™ Urine Amphetamine/Methamphetamine Screen (AMPH)Flex® reagent cartridge
Dimension Vista™ Urine Barbiturates Screen (BARB) Flex® reagent cartridge
Dimension Vista™ Urine Benzodiazepines Screen (BENZ) Flex® reagent cartridge
Dimension Vista™ Urine Cocaine metabolite Screen (COC) Flex® reagent cartridge
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Dimension Vista™ Urine Methadone Screen (METH) Flex® reagent cartridge
Dimension Vista™ Urine Opiates Screen (OPI) Flex® reagent cartridge
Dimension Vista™ Urine Phencyclidine Screen (PCP) Flex® reagent cartridge
Dimension Vista™ Urine Cannabinoids Screen (THC) Flex® reagent cartridge
Regulation Number: 21 CFR§862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHS, LCP, DKZ, DIS, JXM, DIO, DJR, DJG, LCM, LDJ
Dated: July 25, 2006
Received: July 26, 2006

Dear Ms. Piestrak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Creatine Kinase MB Isoenzyme (CKMB) Flex® reagent cartridge

Indications For Use:

The Dimension Vista™ Creatine Kinase MB Isoenzyme (CKMB) Flex® reagent cartridge is a device intended to measure the activity of the creatine kinase MB isoenzyme in plasma and serum. Measurements of creatine kinase MB isoenzyme are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Hemoglobin A1c Kit (HA1C)

Indications For Use:

The HA1C assay used on the Dimension Vista™ integrated system is an *in-vitro* diagnostic assay for the quantitative determination of percent hemoglobin A1c(HbA1c) in anticoagulated whole blood. Measurements of percent hemoglobin A1c are effective in monitoring long term glucose control in individuals with diabetes mellitus.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Urine Amphetamine/Methamphetamine Screen (AMPH) Flex® reagent cartridge

Indications For Use:

The AMPH Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of amphetamines in human urine using a cutoff of either 300, 500, or 1000 ng/mL. Measurements obtained with the AMPH method are used in the diagnosis and treatment of amphetamines use or overdose.

The AMPH method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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510(k) K062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Urine Barbiturates Screen (BARB) Flex® reagent cartridge

Indications For Use:

The BARB Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of barbiturates in human urine. Measurements obtained with the BARB method are used in the diagnosis and treatment of barbiturates use or overdose.

The BARB method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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Office of In Vitro Diagnostic Device Evaluation and Safety

K062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Urine Benzodiazepines Screen (BENZ) Flex® reagent cartridge

Indications For Use:

The BENZ Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of benzodiazepines in human urine. Measurements obtained with the BENZ method are used in the diagnosis and treatment of benzodiazepines use or overdose.

The BENZ method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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510(k) K062128

Indications for Use

510(k) Number (if known): k062128

Device Name: Dimension Vista™ Urine Cocaine metabolite Screen (COC) Flex® reagent cartridge

Indications For Use:
The COC Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine using a cutoff of 150 or 300 ng/mL. Measurements obtained with the COC method are used in the diagnosis and treatment of cocaine use or overdose.

The COC method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

k062128

Indications for Use

510(k) Number (if known): k062128

Device Name: Dimension Vista™ Urine Ecstasy Screen (EXTC) Flex® reagent cartridge

Indications For Use:

The EXTC Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of methylenedioxymethamphetamine (MDMA), and closely related drugs in human urine using a cutoff of either 300 or 500 ng/mL. Measurements obtained with the EXTC method are used in the diagnosis and treatment of ecstasy use or overdose.

The EXTC method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

k062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Urine Methadone Screen (METH) Flex® reagent cartridge

Indications For Use:

The METH Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of methadone in human urine. Measurements obtained with the METH method are used to detect methadone use or overdose and to determine compliance with methadone maintenance treatment.

The METH method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

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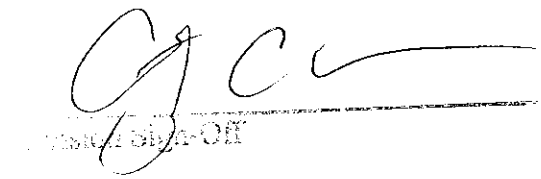

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Office of In Vitro Diagnostic Device
Evaluation and Safety

K062128

Indications for Use

510(k) Number (if known): K062128

Device Name: Dimension Vista™ Urine Opiates Screen (OPI) Flex® reagent cartridge

Indications For Use:

The OPI Flex® reagent cartridge (300 ng/mL cutoff) used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of opiates in human urine. Measurements obtained with the OPI method are used in the diagnosis and treatment of opiates use or overdose.

The OPI method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062128

Indications for Use

510(k) Number (if known): K062124

Device Name: Dimension Vista™ Urine Phencyclidine Screen (PCP) Flex® reagent cartridge

Indications For Use:

The PCP Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of phencyclidine in human urine. Measurements obtained with the PCP method are used in the diagnosis and treatment of phencyclidine use or overdose.

The PCP method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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Office of In Vitro Diagnostic Device Evaluation and Safety

K062124

Indications for Use

510(k) Number (if known): K062121

Device Name: Dimension Vista™ Urine Cannabinoids Screen (THC) Flex® reagent cartridge

Indications For Use:

The THC Flex® reagent cartridge used on the Dimension Vista™ integrated system provides reagents for an *in-vitro* diagnostic test intended for the qualitative and semi-quantitative determination of cannabinoids in human urine. Measurements obtained with the THC method are used in the diagnosis and treatment of cannabinoids use or overdose.

The THC method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801)

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